Quick Start Guides
Work Group Charter

WORK GROUP TOPIC:

Developing Quick Start Guides to facilitate and expand implementation and increase utilization of the Unique Device Identifier (UDI) across the health care supply chain and in electronic health information.

CHARTER:

Develop a series of Quick Start Guides that will assist stakeholders in implementing and expanding the usage of the UDI and associated data standards as part of supply chain and clinical integration programs. The work group will gather input from the community and prioritize the topics for the Quick Start Guide and create a standardized template that each guide will follow. The guides should be 1-2 pages, graphically oriented and incorporate information previously developed with links to more in-depth content. The work group will be responsible for evaluating existing information and creating new content required. The guides would stand alone but could be compiled into an educational booklet. The work group will initially form three subgroups. Two subgroups will focus on health care providers with one addressing supply chain operations and the other clinical operations. The third subgroup will develop a Quick Start Guide for suppliers related to UDI core data requirements. Subsequent guides will address expanding supplier, distributor and other stakeholders' use of the UDI.

BACKGROUND:

September 24, 2022, was the last of a roll out period of FDA CDRH regulatory compliance dates aimed at including UDIs on regulated medical devices. While there are devices exempted from or not subject to the UDI rule, health care providers should expect that UDIs now appear in scannable format on the vast majority of medical device packaging and that manufacturers have submitted UDI-related device attributes to the Global UDI Database (GUDID), made publicly available at AccessGUDID. Despite the relatively ubiquitous nature of UDI, health care providers have been slow to integrate utilization of the UDI into their supply chain and clinical systems and processes. The challenges of integration between various IT systems have added to the implementation burden for providers. Additionally, many manufacturers have met the technical requirements to be compliant but are not maximizing utilization of the UDI within their own systems and processes. Therefore, for many reasons, the myriad benefits of UDI, including improved patient safety and increased supply chain efficiency, are not being fully realized.

Feedback from various stakeholder groups indicated that they were often overwhelmed by long, detailed implementation documents and were having difficulty prioritizing and implementing the steps they could take to start incorporating the UDI into their operations. The idea of creating the Quick Start Guides was based on this feedback.

AFFECTED STAKEHOLDERS:

- Health care providers
- Clinicians
- Patients
- Manufacturers
- Distributors
- ERP Software Providers
- EHR Software Providers
- Inventory Management Software Providers
- Data Management Companies
- FDA
- ONC
- CMS

REQUIRED STAKEHOLDERS:

- Representatives from the Affected Stakeholders group (excluding patients)
- GS1 and HIBCC
- Group Purchasing Organizations

WORK GROUP LEADERS:

- Supply Chain Operations: Carl Gomberg, Premier
- Clinical Operations: TBD
- Core UDI Data Elements: Terrie Reed, Symmetric Health Solutions, Cynthia Shumway, Director Business Operations, Intermountain Health

DELIVERABLES:

- Quick Start Guides

COMMUNICATION PLAN:

Develop and execute a communication plan in collaboration with SMI. Activities would include but not limited to:

- Posting the Quick Start Guides on the AHRMM LUC and the SMI websites
- Presentations at AHRMM and SMI conference
- Webinars and Podcasts
- Distribution to other health care professional organizations such as AIM, AORN, HIDA, HIMSS and others